Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: 3989

Product Description: Corning ® Osteo Assay 1 x 8 stripwell plate, flat bottom, with Low Evaporation lid

Component Materials:

Strips/Lid	-	Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
Surface	-	Inorganic Coating
Holder	-	Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.

Product Dimensions:

Length of Plate	-	5.025 in.	Diameter of Well @ top	-	.270 in.
Width of Plate	-	3.370 in.	Diameter of Well @ bottom	-	.250 in.
Depth of Well	-	.420 in.	Height with Lid	-	.650 in.
Tolerances of Dimensions	-	+/-. 010 in.	Working Volume per well	-	0.1 - 0.2 mL

Sterilization:

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.*
Sterility Assurance Level: SAL 10^{-6}

Pyrogens:

The product has been tested and has met the criteria established in the current version of ANSI/AAMI ST72: 2002/ (R) 2010: Bacterial Endotoxins - Test methodologies, routine monitoring,and alternatives to batch testing.   Results: < 0.1 EU/mL (< 4EU/device)

Surface Characterization:

Surface is characterized as a propritary inorganic coating. This surface composition has been optimized for Osteoclast pit formation.

Surface Function:

This product has been tested for the attribute of Osteoclast pit formation.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Surface Uniformity:	Optical measurement of surface coating
Visual Attributes:	Visual and microscopic examination of the product.
Packaging:	Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacturing; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.

Rev No: 2